AMENDMENTS TO THE CLAIMS

Please amend claims 2, 10, 12-15, 21, 25, 27, 28, 31, 47, 48, 56, 57, 77, 78, 80, 81, 88, 98 and 101 and please cancel without prejudice or disclaimer claims 3-9, 11, 16-20, 22-24, 26, 29, 30, 32-39, 43, 44, 49-55, 58-76, 87, 89-95, 97 and 100 as follows.

The following listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Original) A process for producing a blood plasma-derived Iαlp composition comprising a mixture of inter-alpha inhibitor protein (Iαl) and pre-alpha protein (Pαl), wherein the Iαl and the Pαl are present in said mixture in a physiological proportion, the process comprising:

isolating from blood plasma a plasma fraction containing Iαl and Pαl, wherein the Iαl and Pαl are present in a physicological proportion; and

purifying the plasma fraction to obtain an Iαlp composition with a purity of Iαlp ranging from about 85% to about 100% pure.

2. (Currently Amended) The process of claim 1, wherein the isolating ~~is by~~ comprises solid phase ~~extaction~~extraction or chromatographing blood plasma.

Claims 3-9. (Cancelled)

10. (Currently Amended) The process of ~~any preceding~~ claim 1, wherein the plasma fraction comprises a side fraction obtained from the purification of clotting factor IX or from the purification of a prothrombin complex concentrate.

11. (Cancelled)

12. (Currently Amended) The process of ~~any preceding~~ claim 1, wherein the plasma fraction is isolated as a cryosupernatant resulting from cryoprecipitation of blood plasma.

13. (Currently Amended) The process of ~~any preceding~~ claim 1, wherein the plasma fraction is cryo-poor plasma.

14. (Currently Amended) The process of ~~any preceding~~ claim 1, wherein the plasma fraction is human, primate, bovine, porcine, feline, or canine.

15. (Currently Amended) The process of ~~any preceding~~ claim 1, further comprising obtaining blood, obtaining blood plasma, obtaining a side fraction obtained from the purification of clotting factor IX, obtaining a side fraction from the purification of a prothrombin complex concentrate, obtaining a cryosupernatant resulting from cryoprecipitation of blood plasma or obtaining cryo-poor plasma.

Claims 16-20. (Cancelled)

21. (Currently Amended) The process of ~~any preceding~~ claim 1, wherein the purifying is by hydroxylapatite chromatography, affinity chromatography or a combination thereof.

Claims 22-24. (Cancelled)

25. (Currently Amended) The process of ~~any preceding~~ claim 1, wherein the IαI and PαI present in the plasma fraction have an apparent molecular weight of between about 60,000 to about 280,000 kDa.

26. (Cancelled)

27. (Currently Amended) The process of ~~any preceding~~ claim 1, further comprising: further purifying the plasma fraction; virus inactivating the plasma fraction and/or the purified Iαlp; the addition of stabilizers; comprising pasteurization of the purified Iαlp; or anion-exchange chromatography of the purified Iαlp.

28. (Currently Amended) The process of claim 27, wherein: the further purifying the plasma fraction is by passing ~~to~~through heparin affinity column and collecting the flow through (unbound) fraction; the virus inactivating is by a solvent/detergent treatment or thermal inactivation; and the anion-exchange chromatography of the purified Iαlp isDEAE Sepharose.

Claims 29-30. (Cancelled)

31. (Currently Amended) The process of claim ~~30~~28, wherein the thermal inactivation ~~is~~comprises pasteurization at a temperature of between about 55 to about 65˚C or dry heat at 70 to 120˚C.

Claims 32-39. (Cancelled)

40. (Original) A composition of Iαlp comprising a mixture of inter-alpha inhibitor protein (Iαl) and pre-alpha protein (Pαl), wherein the Iαl and the Pαl are present in said mixture in a physiological proportion ranging from about 85% to about 100% pure.

41. (Original) The composition of claim 40, wherein the Iαlp comprises between about 60% to about 80% Iαl and between about 40% to about 20% Pαl.

42. (Original) The composition of claim 40, wherein the physiological proportion is the ratio of Iαl to Pαl that appears naturally in human plasma.

Claims 43-44. (Cancelled).

45. (Original) The composition of claim 40, further comprising a stabilizing agent.

46. (Original) The composition of claim 45, wherein the stabilizing agent is albumin, polyethylene glycol, alpha,alpha-trehalose, amino acids, salts, glycerol, omega-amino acids, sugar, or combinations thereof.

47. (Currently Amended) A composition of IαIp comprising a mixture of inter-alpha inhibitor protein (IαI) and pre-alpha protein (PαI), wherein the IαI and the PαI are present in said mixture in a physiological proportion and: have a high trypsin inhibitory specific activity; have a half life of greater than one hour; comprise a light chain of inter-alpha inhibitor protein associated with at least one of three heavy chains H1, H2 and H3; or comprise a light chain of inter-alpha inhibitor protein associated with at least one of three heavy chains H1, H2, H3 and H4.

48. (Currently Amended) The composition of claim 47, wherein the ~~IαIp comprises between about 60% to about 80% IαI and between about 40% to about 20% PαI~~the trypsin inhibitory specific activity is between about 1000 to about 2000 IU/mg.

Claims 49-55. (Cancelled)

56. (Currently Amended) The composition of claim [54]47, wherein the IαIp composition has a half life of at least 5 hours.

57. (Currently Amended) The composition of claim [54]47, wherein the IαIp composition has a half life of at least 10 hours.

Claims 58-76. (Cancelled)

77. (Currently Amended) A composition of IαIp comprising a mixture of inter-alpha inhibitor protein (IαI) and pre-alpha protein (PαI), wherein the IαI and the PαI are

present in said mixture in a physiological proportion ~~that is made~~, said composition having been prepared by the process according to ~~any of~~ claim[s] 1[-39].

78. (Currently Amended) The composition of ~~any of~~ claim[s] 40[-77], further comprising an additional therapeutic agent.

79. (Original) The composition of claim 78, wherein the additional therapeutic agent is an anticancer agent, an anti-inflammatory agent, an anti-coagulant or an immunmodulator.

80. (Currently Amended) A pharmaceutical composition comprising a therapeutically effective amount of the composition of ~~any of~~ claim[s] 40~~, 47, 54, 63, 70 or 77~~ and a pharmaceutically acceptable carrier.

81. (Currently Amended) A method of treating an inflammation related disorder, cancer, or an infectious disease in a subject comprising, administering a therapeutically effective amount of ~~Iαlp produced by the process of any~~the composition of claim[s 1-39]40 or 77.

82. (Original) The method of claim 81, wherein the Iαlp is isolated from a subject.

83. (Original) The method of claim 82, wherein the subject is a human, cow, pig, goat, or primate.

84. (Original) The method of claim 81, wherein the Iαlp is administered as a tablet, capsule, or injectables.

85. (Original) The method of claim 81, wherein the Iαlp is at least 85% pure.

86. (Original) The method of claim 81, wherein the Iαlp is between about 85% to about 100% pure.

87. (Cancelled)

88. (Currently Amended) A method of treating a subject for acute inflammatory disease, sepsis, severe shock, septic shock, rheumatoid arthritis, cancer, cancer metastasis, infectious disease, or preterm labor, comprising:

(a) determining the pre-treatment level of one or more of the following levels in a subject:

(i) the level of IαI;

(ii) the level of PαI;

(iii) the level of IαIp;

(iv) the level of H3;

(v) the level of H4;

(vi) the level of H1;

(vii) the level of H2; and

(viii) the level of LC; and

(b) administering a therapeutically effective amount of ~~IαIp~~the composition of claim 40 or 77 to the subject.

Claims 89-95 (Cancelled)

96. (Original) A method for predicting a response to an IαIp therapy, comprising:

assaying a sample obtained from a subject to detect the level of one or more of the following:

(i) IαI;

(ii) PαI;

(iii) IαIp;

(iv) H3;

(v) H4;

(vi) H1;

(vii) H2; and

(viii) LC;

wherein the detected levels identifies a subject that may respond favorable to Iαlp therapy.

97. (Cancelled)

98. (Currently Amended) A method of monitoring the progress of a subject being treated with an Iαlp therapy, comprising:

(a) determining the pre-treatment level of one or more of the following levels, in a subject:

(i) the level of Iαl;

(ii) the level of Pαl;

(iii) the level of Iαlp;

(iv) the level of H3;

(v) the level of H4;

(vi) the level of H1;

(vii) the level of H2; and

(viii) the level of LC;

(b) administering a therapeutically effective amount of ~~Iαlp~~the composition of claim 40 or 77 to the subject; and

(c) determining the level of one or more of the levels in the subject after an initial period of treatment with ~~Iαlp~~the composition,

wherein an increase of the level in the subject following treatment with ~~Iαlp~~the composition indicates that the subject is likely to have a favorable clinical response to treatment with Iαlp.

99. (Original) A kit for Iαlp therapy comprising one or more of the following:

(i) Iαl;

(ii) Pαl;

(iii) Iαlp;

(iv) H3;

(v) H4;

(vi) H1;

(vii) H2; and

(viii) LC; and

instructions for therapeutic use.

100. (Cancelled)

101. (Currently Amended) A kit comprising a composition ~~of any of~~ according to claim[s] 40~~, 47, 54, 63, 70~~ or 77 and instructions for therapeutic use.